

K222984 BioClean Implant Restorative SystemDec 29, 2022
92 days to decisionK222984 · Product code: **NHA** · Dental
Source: <https://www.510kdatabase.net/k222984/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Sep 28, 2022
Decision date	Dec 29, 2022
Days to decision	92 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bioclean Dental, LLC
Location	Jupiter, FL, US
Contact	Russ Bonafede
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	PaxMed International, LLC
Contact	Melissa Burbage

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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